IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
MISSOULA DIVISION

ST. LUKE COMMUNITY HEALTH CARE,

Plaintiff,

vs.

KATHLEEN SEBELIUS, as Secretary of the United States Department of Health and Human Services, MICHELLE SNYDER, as Acting Administrator of the Centers for Medicare and Medicaid, NORIDIAN ADMINISTRATIVE SERVICES, and BLUECROSS BLUE SHIELD ASSOCIATION,

Defendants.

CV 09-92-M-DWM-JCL

FINDINGS AND RECOMMENDATION OF UNITED STATES MAGISTRATE JUDGE

St. Luke Community Health Care ("St. Luke") brings this action to obtain review of a final decision by the Secretary of the United States Department of Health and Human Services ("Secretary") denying St. Luke's claim for reimbursement of certain health care costs under the Medicare health insurance program. 42 U.S.C. § 1395 et seq. The matter is before the Court on the parties' cross-motions for summary judgment under Fed. R. Civ. P. 56. For the reasons

discussed below, the Court recommends that Defendants' motion be granted, and St. Luke's motion be denied.

I. BACKGROUND

St. Luke operates a health care facility located in Ronan, Montana. The facility is designated as a Critical Access Hospital - within the meaning of the Medicare program - that provides health care services to Medicare beneficiaries. As part of its operation, St. Luke contracts with local certified registered nurse anesthetists to provide 24-hour anesthesia services.

The subject of this action arises from St. Luke's claim, under the Medicare program, for reimbursement of costs it incurred in 2004 for certified registered nurse anesthetists. Specifically, the costs at issue include compensation paid to the nurses for being on-call, but located off-site, i.e. not at St. Luke's hospital. On April 23, 2009, the Secretary issued a final decision denying St. Luke's claim for reimbursement of the referenced costs.

As an initial matter, the Court reviews the Medicare insurance program and the scheme for reimbursement of Medicare costs in order to place the parties' dispute in proper context.

A. Medicare Insurance Program and Reimbursable Costs

Congress established Medicare as a federally funded program providing health insurance coverage for elderly and disabled individuals. 42 U.S.C. § 1395 et seq.; Pub. L. 89-97 (Health Insurance for the Aged Act). *See Vitality Rehab v. Sebelius*, 641 F. Supp. 2d 984, 987 (C.D. Cal. 2009). Under the Medicare program, designated health care providers who furnish services to eligible individuals can obtain reimbursement for certain services provided. *Grays Harbor Public Hospital District No. 1 v. Leavitt*, 2007 WL 43027773, *1 (W.D. Wash. 2007).

1. Statutory and Regulatory Provisions

Medicare service providers are eligible for reimbursement of "the reasonable cost" of some services they provide. 42 U.S.C. § 1395f(b)(1); *Robert F. Kennedy Medical Center v. Leavitt*, 526 F.3d 557, 558 (9th Cir. 2008). Providers can obtain reimbursement under alternative methods. Most providers are reimbursed under the prospective payment system which provides reimbursement based on an established amount regardless of the provider's actual cost in providing the health care service. *Grays Harbor*, 2007 WL 43027773, *1 (citing 42 U.S.C. § 1395ww(d)). Certain care providers, including small, rural

hospitals certified as Critical Access Hospitals, can obtain reimbursement based on their "reasonable costs." *Id.*; 42 C.F.R. § 413.1(d).

Congress defined "reasonable cost," in part, as follows:

> The reasonable cost of any services shall be the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs for various types or classes of institutions, agencies, and services[.] [...] Such regulations shall (i) take into account both direct and indirect costs of providers of services (excluding therefrom any such costs, including standby costs, which are determined in accordance with regulations to be unnecessary in the efficient delivery of services covered by the insurance programs established under this subchapter) in order that, under the methods of determining costs, the necessary costs of efficiently delivering covered services to individuals covered by the insurance programs established by this subchapter will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by such insurance programs[.]

42 U.S.C. § 1395x(v)(1)(A).

Congress authorized the Secretary "to issue regulations defining reimbursable costs and otherwise giving content to the broad outlines of the Medicare statute." *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 506 (1994) (citing 42 U.S.C. § 1395x(v)(1)(A)). Section 1395x(v)(1)(A) gives the Secretary discretion to define both the "reasonable costs" of health care services to be reimbursed, and the "items to be included" in the category of reimbursable costs. *Id.*

The Secretary's general regulations governing the reimbursement of reasonable costs related to patient care are set forth in 42 C.F.R. § 413.9. The principle of reimbursement states that:

> [a]ll payments to providers of services must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries. Reasonable cost includes all necessary and proper costs incurred in furnishing the services, subject to principles relating to specific items of revenue and cost.

42 C.F.R. § 413.9(a). "Reasonable cost" includes "both direct and indirect costs and normal standby costs." 42 C.F.R. § 413.9(c)(3). Furthermore, the "[r]easonable cost of any services must be determined in accordance with regulations establishing the method or methods to be used, and the items to be included." 42 C.F.R. § 413.9(b)(1).

"Necessary and proper costs," in turn, are defined as:

> costs that are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities. They are usually costs that are common and accepted occurrences in the field of the provider's activity.

42 C.F.R. § 413.9(b)(2).

The regulations recognize that the costs of services may vary from one provider to another and, therefore, in general the "payment of reasonable cost of services is intended to meet the actual costs." 42 C.F.R. § 413.9(c)(2). This "actual costs" provision, however, does not apply if the actual costs are

"substantially out of line with other" similar institutions and their provision of similar services. *Id*.

The regulations also include provisions specific to services provided at a Critical Access Hospital for both inpatient services (42 C.F.R. § 413.70(a)), and outpatient services (42 C.F.R. § 413.70(b)). Payment for those services is permitted for:

> 101 percent of the reasonable costs of the [Critical Access Hospital] in providing [Critical Access Hospital] services to its [inpatients and outpatients], as determined in accordance with [§ 1395x(v)(1)(A)] and the applicable principles of cost reimbursement in this part and in Part 415 of this chapter[.]

42 C.F.R. § 413.70(a)(1) and (b)(2)(i).

The regulation applicable to the 2004 cost reporting period expressly allowed reimbursement for certain on-call costs as follows:

> (4) Costs of certain emergency room on-call physicians:
>
> > (i) Effective for cost reporting periods beginning on or after October 1, 2001, the reasonable costs of outpatient [Critical Access Hospital] services under paragraph (b) of this section may include amounts for reasonable compensation and related costs for an emergency room physician who is on call but who is not present on the premises of the [Critical Access Hospital] involved, is not otherwise furnishing physicians' services, and is not on call at any other provider or facility.

42 C.F.R. § 413.70(b)(4)(i) (2003).

Finally, the regulations address reimbursement for anesthesia services furnished by "nonphysician anesthetists." 42 C.F.R. § 412.113(c). Payment for these services "is determined on a reasonable cost basis for anesthesia services provided in the hospital or [Critical Access Hospital] by qualified nonphysician anesthetists (certified registered nurse anesthetists and anesthesiologist's assistants)[.]" 42 C.F.R. § 412.113(c)(1) and (2).

2. Medicare Provider Reimbursement Manual

The Centers for Medicare and Medicaid Services ("Centers for Medicare Services")[1] maintain manuals regarding "day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives." Centers for Medicare & Medicaid Services, http://www.cms.gov/Manuals/ (accessed April 9, 2010). Among these manuals is the Medicare Provider Reimbursement Manual ("Reimbursement Manual") which is "published by the Secretary as a guide for providers to determine the 'reasonable cost' of furnishing patient care services to Medicare beneficiaries."

[1]The Centers for Medicare Services is an agency of the United States Department of Health and Human Services which administers the Medicare program on behalf of the Secretary. *Vitality Rehab*, 642 F. Supp. 2d at 987 (citing 42 U.S.C. §§ 1395h and 1395u).

Mercy Hospital and Medical Center, San Diego v. Harris, 625 F.2d 905, 908 n.5 (9th Cir. 1980).

The Reimbursement Manual defines "reasonable costs" using language substantially identical to the definitions set forth in 42 C.F.R. § 413.9.

> Reasonable costs of any services are determined in accordance with regulations establishing the method or methods to be used, and the item to be included. Reasonable cost takes into account both direct and indirect costs of providers of services, including normal standby costs.

Reimbursement Manual § 2102.1. Tr. at 287. The Manual defines "Costs Related to Patient Care" to include:

> all necessary and proper costs which are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities. Necessary and proper costs related to patient care are usually costs which are common and accepted occurrences in the field of the provider's activity. They include personnel costs, administrative costs, costs of employee pension plans, normal standby costs, and others. Allowability of costs is subject to the regulations prescribing the treatment of specific items under the Medicare program.

Reimbursement Manual § 2102.2. Tr. at 287.

The Reimbursement Manual also describes the "[r]eimbursement of hospital emergency department services when physicians receive compensation for availability services." Reimbursement Manual § 2109. Tr. at 289. Under § 2109 "[a]vailability costs [for physicians] will be recognized only in the emergency department of a hospital, and only as described in this section." Reimbursement

Manual § 2109.1. Reimbursement for physician availability costs requires "physical presence of a physician in a hospital[.]" Reimbursement Manual § 2109.2 A.

B. Administrative and Judicial Review

The Centers for Medicare Services contracts with private insurance companies known as "fiscal intermediaries" which are responsible for processing health care providers' claims submitted under the Medicare program. *Vitality Rehab*, 642 F. Supp. 2d at 987. The intermediaries perform audit and payment functions on behalf of the Centers for Medicare Services.

To obtain reimbursement under the Medicare program a health care provider must submit a claim for reimbursement to its fiscal intermediary on an annual cost report. *Vitality Rehab*, 642 F. Supp. 2d at 987; 42 C.F.R. § 405.1801(b). The fiscal intermediary reviews the cost report, and determines the reimbursement payment amounts that are due to the health care provider. *Vitality Rehab*, 642 F. Supp. 2d at 987; 42 C.F.R. § 405.1803.

Federal law under the Medicare program establishes procedures for appealing decisions on reimbursement claims. When a fiscal intermediary denies a health care provider's claim for reimbursement, the provider can appeal the decision to the Provider Reimbursement Review Board ("Reimbursement Board").

42 U.S.C. § 1395oo(a). If the Reimbursement Board grants the claim for reimbursement, then the Secretary can review the Board's decision and issue a final decision. 42 U.S.C. § 1395oo(f)(1). Finally, the provider can obtain judicial review of the Board's decision, or of the Secretary's final decision by filing a civil action in district court. *Id*. *See Vitality Rehab*, 641 F. Supp. 2d at 987-88.

C. Factual and Procedural Background

St. Luke filed this action seeking judicial review of the Secretary's April 23, 2009 decision denying St. Luke's claim for reimbursement of its costs for Certified Registered Nurse Anesthetists' ("Nurse Anesthetists") on-call services. The costs were incurred in the cost reporting year ending December 31, 2004.

St. Luke submitted its 2004 cost report to its fiscal intermediary which, at that time, was Blue Cross and Blue Shield of Montana ("Blue Cross"). St. Luke reported its Nurse Anesthetist costs which included compensation provided to the Nurse Anesthetists for being off-site but available to St. Luke on an on-call basis. St. Luke requested reimbursement for Medicare's share of these costs.

On September 14, 2006, Blue Cross issued its decision with respect to St. Luke's cost report. Blue Cross concluded that the Nurse Anesthetist costs for on-call services were not reimbursable under Medicare, and it denied St. Luke's request for reimbursement of those costs. The net result for St. Luke was a loss of

Medicare reimbursement in the amount of $29,679.

St. Luke appealed Blue Cross's decision to the Reimbursement Board. On February 25, 2009, the Reimbursement Board issued its decision reversing Blue Cross's decision. The Board characterized St. Luke's Nurse Anesthetist on-call costs as "standby costs," and concluded the applicable statutes and regulations allowed reimbursement of those standby costs.

The Secretary appealed the Reimbursement Board's decision to the Administrator of the Centers for Medicare Services. On April 23, 2009, Michelle Snyder, Acting Deputy Administrator, issued her decision reversing the Reimbursement Board's decision, concluding that St. Luke's Nurse Anesthetist on-call costs were not reimbursable under the Medicare program. Having considered the "reasonable cost" and "necessary and proper costs" provisions of 42 U.S.C. § 1395x(v)(1)(A), 42 C.F.R. § 413.9(a) and (b), and 42 C.F.R. § 413.70(a) and (b), the Deputy Administrator concluded the Nurse Anesthetist on-call costs are not expressly included within those reasonable cost provisions.

The Deputy Administrator also noted that the reasonable cost provisions do not identify "[Nurse Anesthetist] 'standby' costs as a reasonable cost." Tr. at 5.[2]

[2]The Deputy Administrator clarified, however, that "standby costs are not equivalent to on-call service costs for Medicare purposes." Tr. at 5.

Rather, the Deputy Administrator pointed out the regulations must exclude "costs, including standby costs, which are determined in accordance with regulations to be unnecessary in the efficient delivery of services covered by the insurance programs established under this title[.]" Tr. at 5 (quoting 42 U.S.C. § 1395x(v)(1)(A)) (emphasis added).

Despite the exclusion of "standby costs" as stated under § 1395x(v)(1)(A), the Deputy Administrator recognized that 42 C.F.R. § 413.9(c)(3) declares that "reasonable costs" can include "normal standby costs." Tr. at 5. The Administrator relied on the Reimbursement Manual at § 2102.1 which describes "standby costs [...] as those attributable to unoccupied beds[.]" Tr. at 5-6. The Administrator noted that the allowable "standby costs" are only those "related to the provider's physical plant or structure and not related to the personnel staffing the hospital." Tr. at 6. Therefore, she concluded the Nurse Anesthetist costs are not reimbursable as standby costs.

The Deputy Administrator proceeded to consider whether St. Luke's costs qualified as "availability" costs. She noted, however, "costs for 'availability' of personnel and costs for personnel to be on-call are only allowable as defined in [ ] § 2109 [of the Reimbursement Manual] and 42 C.F.R. § 413.70(b)(4)." Tr. at 6. Consequently, the Deputy Administrator concluded that the Nurse Anesthetist

costs presented in St. Luke's "cost report as 'standby costs' are not a cost of services provided and are not allowable as either 'availability' costs or as 'on-call' costs." Tr. at 6. Under § 2109.1 of the Reimbursement Manual, "availability costs" are allowed only for the "emergency department of a hospital, and only as described in this section." *Id*. Under § 2109.2 of the Reimbursement Manual, "availability" is defined as the physical presence of a physician in a hospital. *Id*. These permissible "availability" costs in an emergency room were intended to assure "physician availability in that setting." *Id*. Costs for the "availability" of any other personnel in the emergency room, or anywhere else in the hospital, are not reimbursable. *Id*. Thus, the Administrator found St. Luke's Nurse Anesthetist costs are not reimbursable as "availability" costs.

The Deputy Administrator next considered whether St. Luke's costs were "on-call" costs. She declared that the only reimbursable on-call costs are those described in 42 C.F.R. § 413.70(b)(4) which includes only the on-call costs of an emergency room physician. Tr. at 6. Consequently, the Administrator concluded that "[t]he cost for any other on call personnel not specified in the regulations[, such as Nurse Anesthetists,] is not an allowable cost." Tr. at 7.

Finally, the Deputy Administrator addressed the provisions of 42 C.F.R. § 412.113(c). Although § 412.113(c) allows for reimbursement of reasonable costs

for nonphysician anesthetists, the Deputy Administrator stated the provision must be read in the context of the general reasonable cost regulations. Since the "reasonable cost" definition does not include the Nurse Anesthetist costs claimed by St. Luke, those "standby costs [...] cannot be found to be reasonable [Nurse Anesthetist] costs." Tr. at 7.

The Deputy Administrator's decision constitutes the final decision of the Secretary.

II. SUMMARY JUDGMENT STANDARDS

Summary judgment is proper when the "pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In deciding a motion for summary judgment, the court views the evidence in the light most favorable to the non-moving party and draws all justifiable inferences in the non-moving party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). When presented with cross-motions for summary judgment on the same matters, the court must "evaluate each motion separately, giving the non-moving party the benefit of all reasonable inferences." *American Civil Liberties Union of Nevada v. City of Las Vegas*, 333 F.3d 1092, 1097 (9th Cir. 2003).

III. ANALYSIS

A. Standard of Review

This Court's jurisdiction and authority for judicial review in this action is set forth at 42 U.S.C. § 1395oo(f)(1). Subsection (f)(1) establishes that judicial review must be conducted pursuant to the applicable provisions of the Administrative Procedures Act (APA), 5 U.S.C. § 701 et seq.

The APA requires a reviewing court to "decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action." 5 U.S.C. § 706. In particular, a court has authority to "hold unlawful and set aside agency action, findings, and conclusions found to be – (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[, or...] (E) unsupported by substantial evidence[.]" 5 U.S.C. § 706(2)(A) and (E). *See also Vitality Rehab*, 641 F. Supp. at 989 (quoting *Lodi Community Hospital v. Shalala*, 94 F.3d 1251, 1252-53 (9th Cir. 1996)). The arbitrary and capricious standard is "highly deferential, presuming the agency action to be valid and affirming the agency action if a reasonable basis exists for its decision." *Vitality Rehab*, 641 F. Supp. 2d at 989 (quoting *Ranchers Cattlemen Action Legal Fund United Stockgrowers of America v. United States Dept. of Agriculture*, 499 F.3d 1108, 1115 (9th Cir. 2007)).

The arbitrary and capricious test permits only a narrow scope of review - limiting the court to a determination of "whether the agency articulated a rational connection between the facts found and the choice made." *Arizona Cattle Growers Association v. United States Fish & Wildlife Service*, 273 F.3d 1229, 1236 (9th Cir. 2001). "As long as the agency decision was based on a consideration of the relevant factors and there is no clear error of judgment, the reviewing court may not overturn the agency's action as arbitrary and capricious." *Arizona Cattle Growers*, 273 F.3d at 1236 (citation omitted). "The court is not empowered to substitute its judgment for that of the agency." *Arrington v. Daniels*, 516 F.3d 1106, 1112 (9th Cir. 2008) *(quoting Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971)).

Under § 706(2)(E), "[s]ubstantial evidence is 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Vitality Rehab*, 641 F. Supp. 2d at 989 (quoting *Consolo v. Federal Maritime Commission*, 383 U.S. 607, 619-620 (1966)). Nonetheless, the court may not simply rubber-stamp agency factfinding - the APA requires "meaningful review." *Dickinson v. Zurko*, 527 U.S. 150, 162 (1999).

When the issue under an APA analysis is whether a federal agency properly interpreted its own regulation, the federal court must give substantial deference to

an agency's interpretation. *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994). The courts are not to "decide which among several competing interpretations best serves the regulatory purpose. Rather, the agency's interpretation must be given 'controlling weight unless it is plainly erroneous or inconsistent with the regulation.'" *Id*. (citation omitted). Deference to the Secretary's interpretation of a regulation is appropriate "unless an 'alternative reading is compelled by the regulation's plain language or by other indications of the Secretary's intent at the time of the regulation's promulgation.'" *Id*. (citation omitted).

> This broad deference is all the more warranted when, as here, the regulation concerns "a complex and highly technical regulatory program," in which the identification and classification of relevant "criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns."

Thomas Jefferson, 512 U.S. at 512 (citation omitted).

Notwithstanding the deference to which the Secretary's interpretation is entitled, the court must still ensure that the interpretation is reasonable in light of the regulation's plain language, and its prior interpretations and applications. "The interpretation must sensibly conform to the purpose and wording of the regulations." *St. Elizabeth Community Hospital v. Heckler*, 745 F.2d 587, 592 (9th Cir. 1984).

B. Analysis of the Secretary's Decision

St. Luke offers essentially three arguments in support of its contention that the Secretary's decision was arbitrary and capricious. First, St. Luke argues its Nurse Anesthetist on-call costs fall within the general category of reasonable costs that are reimbursable under the Medicare program.

Second, St. Luke asserts the costs are reimbursable because they are not expressly excluded from the category of reimbursable costs. It contends the Secretary construed inapplicable statutory and regulatory provisions, and improperly interpreted those provisions to conclude St. Luke's on-call costs are not reimbursable.

Finally, St. Luke asserts the Secretary had a history of reimbursing Nurse Anesthetist on-call costs, but her decision in this case arbitrarily discontinued those reimbursements.

Upon examination, the Court finds none of the arguments to be persuasive.

1. General Reimbursement and Reasonable Cost Provisions

In support of its position that the Nurse Anesthetist on-call costs are reimbursable, St. Luke relies primarily on the general "reasonable cost" Medicare provisions at 42 U.S.C. § 1395x(v)(1)(A), and 42 C.F.R. § 413.9(a), (b) and (c) quoted above. The Secretary, however, properly concluded that those provisions

do not expressly allow reimbursement for Nurse Anesthetist on-call costs. The Secretary's decision properly recognizes that the general provisions do not permit reimbursement of all reasonable costs across the board. Rather, the reasonable costs which are reimbursable "shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs for various types or classes of institutions, agencies, and services[.]" 42 U.S.C. § 1395x(v)(1)(A). Therefore, the Secretary's decision on this point is not subject to reversal under the APA standards.

St. Luke also argues the Nurse Anesthetist on-call costs are reimbursable as "normal standby costs" within the contemplation of 42 C.F.R. § 413.9(c)(3) and § 2102.2 of the Reimbursement Manual. St. Luke's reliance on the regulations is misplaced. Standby costs are distinguished from on-call costs, and refer to the costs of a care provider who is present at the facility, not a provider who is on-call off-site. *See* footnote 3, infra. The Secretary's decision with respect to subsection (c)(3) and § 2102.2 is not arbitrary or capricious.

St. Luke next relies on two additional statutory provisions which it asserts allow for the reimbursement of its Nurse Anesthetist on-call costs. First, 42 U.S.C. § 1395f(l)(1) (inpatient services) provides that "the amount of payment under this part for inpatient critical access hospital services is equal to 101 percent

of the reasonable costs of the critical access hospital in providing such services." Second, 42 U.S.C. § 1395m(g)(1) (outpatient services) states that "[t]he amount of payment for outpatient critical access hospital services of a critical access hospital is equal to 101 percent of the reasonable costs of the hospital in providing such services[.]" St. Luke contends the terms of these two provisions permit, and do not prohibit reimbursement of Nurse Anesthetist on-call costs.

Sections 1395f(l)(1) and 1395m(g)(1) provide the statutory authority for 42 C.F.R. § 413.70(a)(1) and (b)(2)(i), respectively. The substance of the statutes is identical to the substance of the respective regulations, and the Secretary addressed the provisions of 42 C.F.R. § 413.70(a)(1) and (b)(2)(i) in her final decision. The Secretary properly concluded that these provisions do not expressly include Nurse Anesthetist on-call costs as reimbursable costs. Again, these reasonable cost provisions are general in nature, and the allowance for reimbursement of specific costs is, instead, to be determined pursuant to other specific regulations. *See* 42 U.S.C. § 1395x(v)(1)(A). The Secretary's decision on these provisions is not arbitrary and capricious.

Contrary to St. Luke's contentions, the Secretary also properly applied the provisions of 42 C.F.R. § 412.113(c)(1) and (2). As stated in those regulations, to be reimbursable the costs of nonphysician anesthesia services must be for those

services "provided in the hospital or [Critical Access Hospital][.]" 42 C.F.R. § 412.113(c)(1) and (2) (emphasis added). Thus, the cost of Nurse Anesthetists to be available to St. Luke on-call while they are off the premises cannot constitute services provided "in the hospital."

St. Luke further argues that the reimbursement of Nurse Anesthetist on-call costs is permitted under 42 C.F.R. § 413.70(a)(3) (inpatient services) and § 413.70(b)(6) (outpatient services). These provisions each allow for the "passthrough of costs of anesthesia services furnished by qualified nonphysician anesthetists[.]" Although subsections (a)(3) and (b)(6) allow reimbursement of certain anesthetists' services, each subsection states that the payment for those services will be "made in accordance with § 412.113(c)." Thus, the services reimbursable under § 413.70(a)(3) and (b)(6) must be services rendered "in the hospital." St. Luke's Nurse Anesthetist on-call costs are not for services provided in St. Luke's hospital.

As additional authority related to nonphysician anesthetists, St. Luke relies on § 2112 of the Reimbursement Manual. Section 2112 permits reimbursement of the cost of services provided by nonphysician anesthetists, and states that reimbursement will be made to the hospital "on a reasonable cost basis." Reimbursement Manual § 2112. Section 2112, however, pertains to "the services

furnished by [a nonphysician anesthetist] in connection with the administration of anesthetic agents[,]" and is silent as to the reimbursement of Nurse Anesthetists' on-call costs. Section 2112 simply does not support a ruling in St. Luke's favor under the APA.

2. Costs Excluded From Reimbursement

The Secretary concluded that St. Luke's Nurse Anesthetist on-call costs are excluded from the scope of those costs that are reimbursable under the Medicare program. St. Luke first challenges this conclusion by asserting that the Secretary cannot disallow reimbursement for a particular cost unless a specific regulation excludes the cost at issue. St. Luke relies on 42 U.S.C. § 1395x(v)(1)(A) which provides that the regulations must exclude costs "which are determined in accordance with regulations to be unnecessary in the efficient delivery of services" covered by the Medicare program. St. Luke asserts that the referenced determination has not been made in this case, and no regulation has been promulgated to exclude Nurse Anesthetist on-call costs from the scope of reimbursable reasonable costs. In this regard, St. Luke references two lists of costs which the Centers for Medicare Services has declared to be "unallowable" costs. *See* Reimbursement Manual §§ 2104 and 2105. St. Luke notes that Nurse Anesthetist on-call costs are not included within either of these lists.

St. Luke accurately represents that no provision of the Medicare statutes or regulations exists which expressly excludes Nurse Anesthetist on-call costs from reimbursement. However, 42 U.S.C. § 1395x(v)(1)(A) does not require that before a cost can be deemed excluded the referenced determination must be made and a regulation must be promulgated excluding the specific cost. Section 1395x(v)(1)(A) leaves room for the exclusion of costs even in the absence of a regulation excluding the cost. The Secretary's conclusion in this case is based on her interpretation of the statutory and regulatory provisions cited in her decision rather than any specific exclusionary regulation.

The Secretary's exclusionary decision in this case is based primarily on her interpretation of 42 C.F.R. § 413.70(b)(4). That section is the only Medicare provision which expressly permits reimbursement for the cost of on-call services, but its express terms allow reimbursement only for the on-call cost of emergency room physicians.

The statutory authority for 42 C.F.R. § 413.70(b)(4) is provided at 42 U.S.C. § 1395m(g)(5). The applicable version of that statute, as it existed in 2004, stated as follows:

(5) Coverage of costs for emergency room on-call physicians

In determining the reasonable costs of outpatient critical access

> hospital services under paragraphs (1) and (2)(A), the Secretary shall recognize as allowable costs, amounts (as defined by the Secretary) for reasonable compensation and related costs for emergency room physicians who are on-call (as defined by the Secretary) but who are not present on the premises of the critical access hospital involved, and are not otherwise furnishing physicians' services and are not on-call at any other provider or facility.

42 U.S.C. § 1395m(g)(5) (2004) (emphasis added). This provision was enacted in 2000, and was made effective as of October 1, 2001.[3]

The Secretary then promulgated 42 C.F.R. § 413.70(b)(4) under authority of 42 U.S.C. § 1395m(g)(5). As of October 1, 2001, and effective through the end of 2004, the regulation provided that:

> the reasonable costs of outpatient [Critical Access Hospital] services under

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[3] Prior to the enactment of 42 U.S.C. § 1395m(g)(5) the Medicare program did not allow reimbursement for physician on-call costs. At that time, "the reasonable cost of [Critical Access Hospital] services to outpatients may not include any costs of compensating physicians who are not present in the facility but are on call." 66 Fed. Reg. 39828-01, 39922 (Aug. 1, 2001). Instead, only the "costs of compensating physicians who are on standby status in the emergency room (that is, physicians who are present and ready to treat patients if necessary)" were reimbursable. *Id*. (emphasis added).

The status of the law prior to 2001 highlights the distinction between "standby" services and "on-call" services. Although St. Luke attempts to characterize its Nurse Anesthetist costs as standby costs, standby services refer only to the services of care providers who are present at a health care facility. St. Luke's Nurse Anesthetist costs at issue in this case are for the cost of the Nurse Anesthetists to be available on-call while they are off the premises of St. Luke's facility. Thus, there is no legal authority for St. Luke's characterization of its costs as standby costs.

> paragraph (b) of this section may include amounts for reasonable compensation and related costs for an emergency room physician who is on call but who is not present on the premises of the [Critical Access Hospital] involved, is not otherwise furnishing physicians' services, and is not on call at any other provider or facility.

42 C.F.R. § 413.70(b)(4)(i) (2003) (emphasis added). An "emergency room physician who is on call" is a "doctor of medicine or osteopathy [...] who is immediately available by telephone or radio contact, and is available onsite" within specified timeframes. 42 C.F.R. § 413.70(b)(4)(ii)(B).

The regulations establish that for the cost reporting period ending December 31, 2004, the only on-call costs that were specifically reimbursable under the Medicare laws and regulations were the on-call costs of physicians in the emergency room department of a hospital. Nurse Anesthetists' on-call costs are not expressly included in either 42 U.S.C. § 1395m(g)(5) or 42 C.F.R. § 413.70(b)(4).[4] The Secretary thus construed and interpreted § 413.70(b)(4) to characterize St. Luke's Nurse Anesthetist on-call costs as costs that are excluded

[4]It is noteworthy that effective January 1, 2005, 42 U.S.C. § 1395m(g)(5) and 42 C.F.R. § 413.70(b)(4)(i) were amended to include, as reimbursable on-call costs, the costs of "physician assistants, nurse practitioners, and clinical nurse specialists" "who are on call but who are not present on the premises[.]" Although this expansion of the care providers for whom on-call costs are reimbursable does not apply to St. Luke's 2004 claim, it is significant in that Congress and the Secretary still did not expand the scope of the provisions to include the on-call costs of Nurse Anesthetists.

from reimbursement.[5]

This Court must give substantial deference to the Secretary's interpretation of her own regulations, and such deference is particularly warranted in the complex area of Medicare reimbursement. To upset this deference, St. Luke must establish that the Secretary's interpretation is plainly erroneous or inconsistent with the regulations. St. Luke could also establish that an alternative reading is compelled by the plain language of the regulation or by the intent behind the promulgation of the regulation.

In questioning the deference to which the Secretary's decision is entitled, St. Luke first complains that 42 C.F.R. § 413.70(b)(4) and § 2109 of the Reimbursement Manual apply only to the on-call costs, and the availability costs, respectively, for emergency room physicians. Therefore, St. Luke argues those provisions are legally inapplicable to the on-call costs associated with Nurse Anesthetists.

The Secretary's decision construes the Medicare provisions at issue to identify emergency room physician on-call costs as the only on-call costs that are

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[5]Additionally, the Secretary noted that under § 2109 of the Reimbursement Manual, the only reimbursable "availability" costs were those incurred for emergency room physicians. Sections 2109.1, 2109.2, and 2109.3 do not provide for the reimbursement of Nurse Anesthetist "availability" costs.

reimbursable under Medicare. This interpretation is not contrary to the plain language of the regulation, and the Court must defer to the Secretary's "exercise of judgment grounded in policy concerns" seeking to prevent the Medicare program from bearing the costs associated with matters not covered by Medicare. *Thomas Jefferson*, 512 U.S. at 512; 42 U.S.C. § 1395x(v)(1)(A). The Secretary's construction of § 413.70(b)(4) is entitled to deference and does not constitute an improper application of an inapplicable regulation.

St. Luke contends the Secretary's interpretation is necessarily contrary to Congress's intent in enacting 42 U.S.C. § 1395m(g)(5), and the Secretary's intent in promulgating 42 C.F.R. § 413.70(b)(4). It argues that Congress and the Secretary did not intend to take away any reasonable cost reimbursements that previously existed, yet the Secretary's interpretation suggests that Congress and the Secretary intended to eliminate the reimbursement of Nurse Anesthetist on-call costs that was previously allowed.

St. Luke, however, has not established that reimbursement for Nurse Anesthetist on-call costs was allowed prior to 2001 when § 1395m(g)(5) and § 413.70(b)(4) became effective. Therefore, there exists no basis for concluding the Secretary's interpretation of these provisions improperly disallows that which was previously allowed, and her interpretation is still entitled to deference.

St. Luke has not demonstrated that the Secretary's interpretation is "plainly erroneous or inconsistent with the regulation[s]" she interpreted. *Thomas Jefferson*, 512 U.S. at 512. The regulatory provisions do not compel an "alternative reading," and the Court finds nothing in the Federal Register expressing a contrary intent at the time § 413.70(b)(4) was promulgated. The Court cannot conclude the Secretary's decision does not "sensibly conform to the purpose and wording of the regulations." *St. Elizabeth Community Hospital*, 745 F.2d at 592. Therefore, the Secretary's interpretation is entitled to substantial deference, and does not warrant reversal under the APA.

3. Prior History of Reimbursing Nurse Anesthetist Costs

In a final effort to salvage its claim for reimbursement, St. Luke argues that prior to 2004 the Secretary consistently reimbursed health care providers for Nurse Anesthetist on-call costs and, therefore, the Secretary's decision to discontinue reimbursement of those costs is arbitrary and capricious. In support of this argument St. Luke relies on the testimony of Shane Roberts, St. Luke's Chief Executive Officer, and David Pfeifle, a Blue Cross employee. Roberts and Pfeifle testified on June 12, 2008, before the Reimbursement Board during the administrative appeal in this case.

Review of Roberts and Pfeifle's testimony reflects that although the

Secretary may have paid some Nurse Anesthetist on-call costs for a period of time, the Secretary did so without recognizing she was reimbursing providers for those costs. As soon as the Secretary recognized she was reimbursing those costs she discontinued such reimbursements.

The Secretary's failure to recognize that Nurse Anesthetist on-call costs were being reimbursed under Medicare was due, in part, to the fact that those costs were not previously expressly reported as "on-call costs." Roberts testified that St. Luke always reported its Nurse Anesthetist on-call costs as "normal expenses, salary expenses" as directed by applicable Medicare instructions. Tr. at 118, 123.

Additionally, Pfeifle testified that "prior to the last three or four years[,]" i.e. prior to 2004 or 2005, the Secretary did not recognize that health care providers were being reimbursed for Nurse Anesthetist on-call costs. Tr. at 120. Prior to 2004 or 2005, the fiscal intermediaries did not address the specific issue of whether Nurse Anesthetist on-call costs were reimbursable. The intermediaries had never reviewed cost reports to determine whether health care providers included Nurse Anesthetist on-call costs in their cost reports, and the intermediaries had not previously made adjustments to cost reports disallowing the on-call costs. Tr. at 120-122, 127. The on-call costs were previously included in cost reports as salary expenses and were reimbursed by the Secretary "because the

issue never came up" prior to 2004 or 2005. Tr. at 122.

The issue of whether St. Luke's Nurse Anesthetist on-call costs were reimbursable first arose in connection with Blue Cross's inquiry into an unrelated matter. Tr. at 126. Through that inquiry, Blue Cross discovered that critical access hospitals were being reimbursed for Nurse Anesthetist on-call costs. Therefore, it sought guidance from the Centers for Medicare Services as to whether the costs were reimbursable. Tr. at 126. Pfeifle testified that Blue Cross received instructions from the Centers for Medicare Services stating that the costs were not reimbursable, and directing the fiscal intermediaries to make adjustments to cost reports to disallow reimbursement for the Nurse Anesthetist on-call costs. Tr. at 121. *See also* Tr. at 260-61 (email dated June 22, 2006 from Pfeifle regarding the new instructions from the Centers for Medicare Services).

The record in this case does not establish that the Secretary knowingly provided reimbursement for Nurse Anesthetist on-call costs prior to disallowing the costs in this case. Once the Secretary discovered that those costs were being reimbursed, the Centers for Medicare Services directed that the intermediaries disallow reimbursement for the on-call costs. Therefore, contrary to St. Luke's assertion, the Secretary's decision in this case does not constitute an arbitrary or capricious decision to discontinue the reimbursements. Her decision is, instead,

explained by the Secretary's delayed recognition that health care providers were including the on-call costs on their cost reports, and that the costs, although unreimbursable, were inadvertently being reimbursed.

IV. CONCLUSION

Upon review of the Secretary's April 23, 2009 decision in this matter, the Court cannot conclude the decision is arbitrary, capricious, an abuse of discretion, not in accordance with law, or unsupported by substantial evidence. Therefore, IT IS HEREBY RECOMMENDED that St. Luke's Motion for Summary Judgment be DENIED, and Defendants' Cross-Motion for Summary Judgment be GRANTED. This action should be DISMISSED.

DATED this 14th day of April, 2010.

/s/ Jeremiah C. Lynch
Jeremiah C. Lynch
United States Magistrate Judge